REMARKS

Status of the Claims

Claims 1-30 are pending in this application, with claims 8, 10, 14, and 16-30 being withdrawn from consideration. All pending claims stand rejected. By this response, Applicants have not amended any claims. Upon entry of this amendment, claims 1-7, 9, 11-13, and 15 will remain pending and under consideration in the application.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1-7, 9, 11, 12 and 15 as being anticipated by U.S. Publ. No. 2003/0199872 (Markworth). In particular, the Examiner states:

> Markworth et al. disclose various embodiments of an implant implantation device comprising a frame having a trigger mechanism, 514, an outer sleeve, 400, mechanically coupled to the frame, an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant, wherein the inner shaft is slidably disposed along a major axis of the inners haft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant, and a retaining spring element, 600, for directing the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released (see figures 6A, 6B, 7A and 7B). The device further includes a drag adjustment screw, 108, rotatably coupled to the frame for providing tension between the trigger mechanism and the inner shaft, and a including a depth control member, 200, slidably coupled to the outer sleeve, wherein the depth control member provides a predetermined insertion depth of the implant (see figures 6A, 6B, 7A and 7B). The device also includes a protrusion, 112, on the outer sleeve for slidably engaging a distraction instrument (see figures 6A, 6B, 7A and 7B). Markworth et al. further disclose a knob, 712, mechanically coupled to the outer sleeve, wherein the knob is capable of causing the outer sleeve and the inner shaft to be rotated about the frame (see figures 7A and 7B and paragraphs 0057-0060). The grabber includes grabber tips for mechanically engaging an implant wherein the grabber tips include a first pair of slots for engaging a first engagement tab of the implant and a second pair of slots for engaging a second engagement tab of the implant and wherein a sizing slot is located between the first pair of slots and the second pair of slots to allow for a

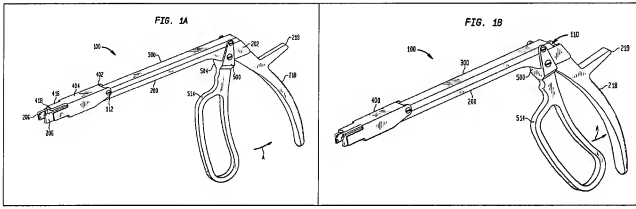
variation of tab and slot dimensional differences (see figure1C). The grabber further includes markings, e.g. 111, to identify a position of an implant, and the grabber is capable of being removably coupled to the inner shaft (see figures 6A, 6B, 7A and 7B).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Markworth et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

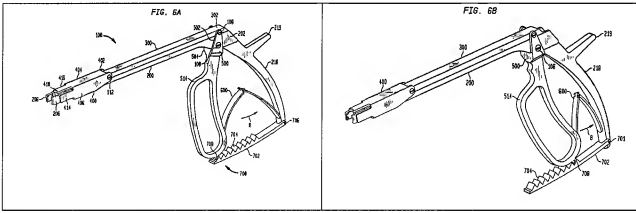
Applicants traverse.

The Markworth Reference

Markworth provides an orthopedic device for urging a spinal fixation rod into a slot in the head of a pedicle screw. Markworth has a handle 218 is fixedly attached to a body 200. [Para. 44.] A trigger 500 connects to a slide 300 to connect the slide to the body. [Para. 48.] A sleeve 400 is connected to the distal end of slide 300. [Para. 50.] In use, fingers 206 provided on the distal end of body 200 engage or grip the head of a pedicle screw. The trigger 500 is then squeezed toward the handle 218, as illustrated in Figures 1A and 1B below, so that slide 300 slides distally on body 200, pushing sleeve 400 distally, which in turn pushes the spinal fixation rod into the head of the pedicle screw. [Para. 51.]



As further illustrated in Figures 6A and 6B, a spring 600 and ratchet 700 are provided to bias the trigger 500 to its "unpulled" position in which the sleeve 400 is retracted:



Markworth Does Not Disclose the Features of Claim 1

The anticipation case for claim 1 as laid out by the Examiner in the Final Office Action is as follows:

Claim 1 Element:	*Correspondence to Markworth per the Office Action:*
i) a frame having a trigger mechanism;	"a frame having a trigger mechanism, 514,"
ii) an outer sleeve mechanically coupled to the frame;	"an outer sleeve, 400, mechanically coupled to the frame,"
iii) an inner shaft having a grabber for mechanically engaging an implant, the inner shaft slidably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the	"an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant," "wherein the inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve," "whereby actuation of the trigger extends the

grabber from the outer sleeve to thereby release the implant; and	grabber from the outer sleeve to thereby release the implant, and"
iv) a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.	a retaining spring element, 600, for directing the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released (see figures 6A, 6B, 7A and 7B).

Because the intended function of Markworth is so different from the claimed device, its structure is so different as to be exactly the opposite of the claimed configuration – making anticipation by Markworth impossible. Not only must "each and every element as set forth in the claim" be found in the prior art reference for anticipation to lie, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), but the elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *See, also*, MPEP § 2131.

In element (ii), the claim requires that the outer sleeve be mechanically coupled to the frame – the cited sleeve 400 in Markworth is not mechanically coupled to the frame, but rather is connected to the distal end of the slide 300 for sliding movement. [Para. 48.] The Examiner refers to this slide 300 as the "inner shaft" of the claims – not the frame – which would presumably correspond to body 200 in the Examiner's scheme. Accordingly, this claim element is not met as the outer sleeve is not mechanically coupled to the frame.

In element (iii), the claim requires that the inner shaft have the grabber – the cited "grabber" 206 in Markworth is not on the "inner shaft" (slide 300, according to the Examiner). Rather, fingers 206 of Markworth (said to correspond to the "grabber") extend from the distal end of the body 200. [Para. 42.] The only element provided on the "inner shaft" 300 is the "outer sleeve" 400 – which does not "grab" anything, but rather pushes on a spinal fixation rod. Accordingly, this claim element is not met as "inner shaft" 300 does not have a "grabber" 206.

The claim goes on to expressly state that the inner shaft (slide 300, according to the Examiner) is slidably disposed within the outer shaft (sleeve 400, according to the Examiner). Markworth does not disclose such a relationship, the sleeve 400 is pivotally connect to the distal end of the slide 300 – it does not and cannot slide with respect to it. [Para. 50.] Accordingly, this portion of the claim element is not met as the "inner shaft" 300 does is not slidably disposed

within "outer sleeve" 400.

Still further in element (iii), the claim requires that actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant. First, squeezing the trigger 514 in Markworth does not move the grabber (fingers 206) at all. The position of the fingers 206 in Markworth is fixed by virtue of their fixed relationship on the distal end of the body 200 – there is no movement at all, much less extension. Second, squeezing the trigger in Markworth pushes sleeve 400 over fingers 206 – rather than being configured to extend the grabber outside out of the outer sleeve upon actuation, Markworth does the opposite of the claim recitation and pushes the sleeve 400 over the fingers 206 when the trigger is actuated. Third, actuating the trigger in Markworth does not "thereby release the implant" – it does nothing to relationship between the grabber and the implant. In Markworth, a force is applied to the body 200 of Markworth to insert the implant between fingers 206 – "the fingers 206 continue to grip" the implant as the spinal fixation rod is oriented, then, after the rod is placed, the user releases the grip of the "grabber" by rotating the instrument in its entirety. [Para. 51.] Again, this recited feature of element (iii) is not met by Markworth – Markworth provides the opposite.

Turning to element (iv), when the claimed trigger is released, a retaining element directs the grabber toward a closed position whereby the grabber is substantially within the outer sleeve. Again, Markworth discloses the exact opposite. Referring to the very Figures cited by the Examiner, it is clear that releasing the trigger 500 (shown released, for example, in Figure 6A above) results in the fingers 206 (which never change their position in response to the trigger) being extended outward – not within – sleeve 400.

At every turn, Markworth discloses, teaches and suggests a structure that is the diametric opposite to that recited. Under these circumstances there can be no anticipation.

The Examiner further states that:

> With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Markworth et al., which is capable of being used as claimed if one so desires to do so.

First, the Examiner does not identify which claim recitation is a "statement of intended use" or "other functional statement."

Second, the Examiner is wrong as a matter of fact. As explained in detail above, the device of Markworth is not "capable of being used as claimed" – rather, the only way in which the Markworth device can is diametrically opposed to the claim recitations.

Third, the Examiner is wrong as a matter of law – to the extent any of the claim recitations relied upon above might be considered by the Examiner to be functional, the law is quite clear that when the prior art device is not capable of performing the recited function, it does not anticipate. As the MPEP and the cases it cites make clear, not only is the use of functional language not improper, but when considered in context through the eyes of a person of ordinary skill in the art, it may serve to precisely define the structural attributes of the claimed invention:

> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). ***There is nothing inherently wrong with defining some part of an invention in functional terms.*** Functional language does not, in and of itself, render a claim improper. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).
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> A ***functional limitation must be evaluated and considered,*** just like any other limitation of the claim, ***for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.*** A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. . . .
>
> In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" ***serve to precisely define present structural attributes of interrelated component parts of the claimed assembly***. In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

(MPEP, § 2173(g) Functional Limitations; emphasis added.) Here, a person of ordinary skill in the art would have no problem understanding exactly the structural attributes of the interrelated

component parts of the claimed assembly. As has been made clear above, the Markworth device cannot meet the claim recitations precisely because of those structural attributes of the interrelated component parts of the claimed assembly.

The Examiner's Response to Arguments

The Examiner, in response to arguments, asserts, relying on Paragraph 51 of Markworth, that the "grabber is substantially contained within the outer sleeve when the trigger is released. Actually, Markworth does the exact opposite. Squeezing the trigger of Markworth causes its sleeve 400 to ride over its fingers 206 – releasing the trigger then results in the fingers 206 extending outside of the sleeve 400. Paragraph 51, cited above in Applicants' arguments, says the exact opposite of what the Examiner says it says.

Even more remarkably, the Examiner cites to lines 31-36 of Paragraph 51 for the proposition that "the actuation of the trigger, 514, does release the coupling element." First of all, at lines 31-36 of Paragraph 51, the trigger is not actuated, it has been released. Second, lines 31-36 state that it is the twisting the instrument, not the actuation of any trigger, that releases the fingers 206 from the implant.

Dependent Claims

Claim 3 depends from claim 1 and further recites a knob mechanically coupled to the outer sleeve and causing the outer sleeve and the inner shaft to be rotated about the frame. Markworth has no such structure, and permits no such rotation. First, the Examiner never identifies the "frame" of the instrument (though most likely it would correspond to body 200 in the Examiner's scheme). The Examiner identifies "a knob, 712 . . . capable of causing the outer sleeve and the inner shaft to be rotated about the frame . . ." Tab 712 of Markworth is capable of no such thing. Tab 712 of Markworth (discussed in Para. 58 and illustrated in Figs. 7A and 7B) extends from the body and provides ratchet teeth 708a for ratcheting the sliding of slide 300 with respect to body 200. It has nothing to do with rotation – and there is no possible way that the "outer sleeve" (sleeve 400 according to the Examiner) and "inner shaft" (slide 300 according to the Examiner) can rotate with respect to any frame (not identified by the Examiner, but possibly body 200) as recited – they slide linearly. Accordingly, claim 3 is separately patentably over

Markworth on this basis.

Claim 5 depends from claim 1 and further recites at least one protrusion on the outer sleeve for slidably engaging a distraction instrument. The Examiner points to screw 112 as this protrusion. Screws 112 attach sleeve 400 to slide 300. [Para. 50.] These screws 112 do not protrude and so cannot be said to anticipate "at least one protrusion." Accordingly, claim 5 is separately patentably over Markworth on this basis.

Claim 6 depends from claim 1 and further recites a depth control member slidably coupled to the outer sleeve for providing a predetermined insertion depth of the implant. The Examiner identifies body 200 as the depth control member. As the position of body 200 of Markworth is fixed to the "grabber" (fingers 206 that extend from the distal end of the body), there is no way that the body can slide so at to provide a predetermined insertion depth of the implant – the body always has exactly the same orientation with respect to the implant. Accordingly, claim 6 is separately patentably over Markworth on this basis.

Claim 12 depends from claim 1 and further recites that the grabber includes at least one marking to identify a position of the implant. The Examiner states that the "grabber further includes markings, e.g. 111, to identify a position of an implant. . ." There is no element numbered 111 in Markworth, and there is no feature on the external surface of the "grabber" of Markworth whatsoever. Accordingly, there is no marking on the grabber to identify the position of anything and claim 12, as well as claims 13 and 14 which depend from claim 12, is separately patentable over Markworth on this basis.

Claim 15 depends from claim 1 and further recites that the grabber is removably coupled to the inner shaft. The Examiner states that "the grabber is capable of being removably coupled to the inner shaft . . ." First, the claim is not premised in terms of capability. Second, the "grabber" of Markworth (fingers 206) never even touch the "inner shaft" (slide 300). The fingers 206 extend from the distal end of body 200 and fit within sleeve 400. The are not coupled to the inner shaft at all – much less removably. Accordingly, claim 15 is separately patentable over Markworth on this basis.

CONCLUSION

Applicants believe that claims 1-7, 9, 11-13 and 15 are in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, she is kindly requested to contact the undersigned.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-719.

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Respectfully submitted,

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